

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

V.

IMPAX LABORATORIES, INC.,

Defendant.

C. A. No. 06-222-JJF

**REDACTED -
PUBLIC VERSION**

**WYETH'S ANSWERING BRIEF IN OPPOSITION TO IMPAX'S MOTION TO
STRIKE PORTIONS OF THE REBUTTAL EXPERT REPORTS
OF DR. HENRY GRABOWSKI AND DR. RONALD THISTED**

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NATURE AND STAGE OF PROCEEDINGS

On December 19, 2007, Impax filed its Motion to Strike Portions of the Expert Reports of Dr. Henry Grabowski and Dr. Ronald Thisted (the "Motion"). (D.I. 320). This is Wyeth's Answering Brief in opposition to that motion.

SUMMARY OF ARGUMENT

Impax's Motion is based on a mischaracterization of the scope of both Wyeth's and Impax's expert reports, as well as a fundamental misunderstanding of Federal Rule of Civil Procedure 26(a)(2) regarding the proper scope of rebuttal evidence. The rebuttal expert reports of Drs. Grabowski and Thisted are proper because they unambiguously rebut subject matter raised by Impax's experts on issues for which Impax bears the burden of proof.¹ For these reasons, as set forth more fully below, Impax's Motion to Strike should be denied in its entirety.

STATEMENT OF FACTS

A. Dr. Grabowski's Expert Report Properly Rebutts the Allegations of Obviousness Raised by Impax's Experts

On September 28, 2007, pursuant to the Court's Scheduling Order, Impax submitted its opening expert reports on the issues for which it has the burden of proof at trial. Among the expert reports it submitted were those of Dr. Arthur Kibbe and Dr. Bert Spilker, both of whom opined on, *inter alia*, the alleged obviousness of the asserted claims of Wyeth's patents-in-suit regarding methods of using extended-release dosage forms of venlafaxine

¹ Impax filed this motion only after Wyeth filed its Motion to Strike Paragraphs 72-73, 81-84, 129-130, and 133-136 of the Rebuttal Expert Report of Arthur H. Kibbe, Ph.D. (D.I. 295), perhaps in an attempt to salvage its own improper rebuttal report by raising criticisms of Wyeth's rebuttal reports. The issues raised by the two motions are entirely different, however. Wyeth's motion relates to Impax's attempt to raise issues for which it bears the burden of proof for the first time in Dr. Kibbe's rebuttal report. In contrast, Drs. Grabowski and Thisted properly responded in their rebuttal reports to subject matter raised by Impax's experts for which Impax bears the burden of proof.

hydrochloride. [See, e.g., Expert Report of Dr. Arthur H. Kibbe at ¶¶ 8-24; Expert Report of Dr. Bert Spilker at ¶¶ 11-14].

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Impax also submitted on that date, the opening expert report of Dr. William S. Comanor which, while apparently conceding that Wyeth's Effexor XR[®] is a commercial success, alleges that

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In response, on October 30, 2007, Wyeth submitted, *inter alia*, the Rebuttal Expert Report of Dr. Henry Grabowski³ which analyzes the extraordinary commercial success of Effexor XR[®],

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as evidence of the nonobviousness of the claimed inventions. Impax argues in its brief that Dr. Grabowski *only* rebuts the expert report of Dr. Comanor, which narrowly focuses on advertising and promotion of Effexor XR[®]. This is incorrect.

Dr. Grabowski's report responds to the broad assertions of obviousness raised by all three of Impax's experts, and discusses, *inter alia*: (1) the extremely competitive nature of the pharmaceutical industry generally, and of the antidepressant market specifically; (2) the extraordinary commercial success of Wyeth's patented extended release venlafaxine product,

² Effexor XR[®] is Wyeth's commercial embodiment of extended release venlafaxine hydrochloride, the use of which is covered by the asserted claims of the patents-in-suit.

³ Dr. Grabowski is an economist from Duke University and an expert on the economics of the pharmaceutical industry.

Effexor XR[®], despite the competitive market; (3) the nexus between the commercial success of Effexor XR[®] and Wyeth's patented inventions; and (4)

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It further explains how Effexor XR[®] has maintained its commercially successful position in the marketplace despite Effexor XR[®]'s late entry into the crowded and competitive antidepressant market, increased competition since Effexor XR[®]'s 1997 launch from both branded and generic competitors, and Effexor XR[®]'s premium price compared to those many competitors. His report also contains background information relevant to his discussion of the competitive antidepressant market, as well as his conclusions regarding commercial success and nonobviousness, including an overview of the economics of the research-based pharmaceutical industry, the costs and risks associated with drug development, and the incentives provided by patents in the innovative process.

As set forth more fully below, all of this proposed testimony is appropriate rebuttal to the allegations of obviousness made by Impax's Drs. Kibbe, Spilker, and Comanor.

B. Dr. Thisted's Rebuttal Expert Report Properly Responds to Issues Raised by Dr. Spilker in His Expert Report and by Dr. Kibbe in Both His Expert Report and Untimely Supplemental Expert Report

Paragraphs 87 and 88 of Dr. Thisted's⁴ Rebuttal Expert Report, which Impax seeks to strike, contain his determination that

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Impax asserts that Dr. Thisted's discussion of

⁴ Dr. Thisted is a statistician from the University of Chicago and is an expert in statistics and biostatistics.

is improper because Impax's experts, Drs. Wecker and Spilker, only discuss clinical Studies 208, 209, and 367 in their respective expert reports. But the three clinical studies that Drs. Wecker and Spilker discussed in their expert reports are directed to an entirely different issue - namely, whether those three clinical studies support Wyeth's claims of diminished incidences of nausea and emesis as between its patented extended release venlafaxine formulation and the immediate release dosage form.

In contrast, paragraphs 87 and 88 of Dr. Thisted's rebuttal report properly respond to assertions raised by Dr. Spilker in his Expert Report and Impax's other expert, Dr. Kibbe, in both his Expert Report and his untimely Supplemental Expert Report. For example, Dr. Spilker opined :

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Dr. Thisted's analysis of
rebutts, in part, these opinions.

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Finally, Impax inaccurately states that “Dr. Thisted admitted that paragraphs 87 and 88 of his rebuttal report did not rebut the opinions of any Impax expert.” [D.I. 320 at 2]. The cited testimony, however, instead states only that Dr. Thisted did not recall whether

was discussed by any of Impax’s experts (Thisted Tr. at 126:15-18), and that he did not recall whether Impax’s experts offered any opinion **REDACTED** in their initial expert reports (Thisted Tr. at 126:4-6). Impax’s counsel never asked Dr. Thisted to identify the issues for which his analysis of / was responsive.

ARGUMENT

A. Impax Applies the Wrong Legal Standard

Citing to Fed. R. Civ. P. 26(a)(2)(C), Impax argues that “[a]n expert’s rebuttal testimony may be offered ‘solely to contradict or rebut’ the *expert testimony* of the opposing party.” (D.I. 320 at 3 (emphasis added)). By cropping the quotation, Impax misstates the rule. Rule 26(a)(2)(C) provides in pertinent part that within 30 days of a party’s initial expert disclosures under Rule 26(a)(2)(B), the opposing party may provide a rebuttal disclosure:

...if the evidence is intended solely to contradict or rebut evidence *on the same subject matter* identified by another party...

Fed.R.Civ.P. 26(a)(2)(C)(emphasis added). Thus, rebuttal testimony is *not* limited to the specific evidence relied upon by the opposing party’s experts, as Impax suggests. Rather, rebuttal testimony is proper so long as it contradicts or rebuts the “same subject matter” raised by the opponent’s expert in an initial expert report. *Id.* As one court has noted, to

determine whether a rebuttal disclosure under Rule 26(a)(2)(C) is proper, it often is helpful to answer three questions:

(1) what evidence does the rebuttal expert contradict or rebut;

(2) is the evidence disclosed as rebuttal evidence on the same subject matter as that identified by another party in its Rule 26(a)(2)(B) disclosure; and

(3) is the evidence disclosed as rebuttal evidence intended to solely contradict or rebut that evidence?

Poly-America, Inc. v. Serrot Int'l. Inc., No. CIV. A. 300CV1457D, 2002 WL 1996561 (N.D. Tex. Aug. 26, 2005). The rebuttal expert reports of Drs. Grabowski and Thisted clearly satisfy this standard.

The cases Impax cites are not to the contrary. Rather, those cases are directed to the scope of permitted rebuttal testimony *at trial*, and do not even address the scope of rebuttal testimony in an expert report under Rule 26(a)(2). For example, in *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 752 F. Supp. 181 (E.D. Pa. 1990), the district court refused to allow rebuttal testimony at trial regarding subject matter that was cumulative to evidence the party already presented in the its case-in-chief. According to the court, “[r]ebuttal testimony in not a vehicle for a party to reemphasize its arguments to a jury prior to deliberation....” *Id.* at 193.

Similarly, in *Emerick v. U.S. Suzuki Motor Corp.*, 750 F.2d 19 (3d Cir. 1984), a product liability action, the Third Circuit noted that the district court was well within its discretion in rejecting proposed expert testimony at trial because “the Emerick’s expert and videotape testimony belonged in its case-in-chief, as the true purpose of such testimony was to demonstrate the defective nature of the motorcycle’s kickstand.” *Id.* at 22.

Neither of these cases addresses Rule 26(a)(2) or the proper scope of an expert's rebuttal expert report in response to an opponent's opening expert reports, and with good reason: as explained below, cases that have addressed the issue support Wyeth.

B. The Rebuttal Expert Reports of Dr. Grabowski and Dr. Thisted are Entirely Appropriate

1. Dr. Grabowski's Rebuttal Expert Report Properly Rebutts the Issue of Obviousness Raised by Impax's Experts

Dr. Grabowski's rebuttal expert report properly rebuts Impax's numerous allegations of obviousness as they appear in Impax's expert reports of Drs. Kibbe, Spilker and Comanor. Among the factors considered in determining whether a patent claim is obvious under § 103 is any objective indicia of nonobviousness -- i.e., the so-called "secondary considerations" which include evidence of commercial success. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662 (Fed. Cir. 2000). Indeed, the Federal Circuit has emphasized that "[o]ur precedents clearly hold that secondary considerations, when present, *must* be considered," and "may often be the most probative and cogent evidence in the record." *Ruiz*, 234 F.3d at 667 (emphasis added). Dr. Grabowski's evidence of commercial success of Effexor XR[®] is, therefore, proper rebuttal testimony to the allegations of obviousness by Impax's experts.

ABB Air Preheater, Inc. v. Regenerative Env'tal Equip. Co., Inc., 167 F.R.D. 668 (D.N.J. 1996), involved the identical issue presented here. There, plaintiff ABB sought to preclude defendant REECO from offering any expert testimony concerning any "secondary considerations," such as commercial success, in response to ABB's allegations of obviousness.⁵

⁵ Due to the posture of the case, the plaintiff ABB was the alleged infringer and the defendant, REECO, was the patentee.

ABB argued, as Impax does here, that “to overcome evidence of ‘obviousness’ in an action challenging the validity of a patent, the patentee bears the burden of establishing secondary considerations of validity or ‘non-obviousness’ in the first instance” and, therefore, REECO’s expert should have set forth his opinions on secondary considerations in an opening expert report. *Id.* at 669.

The district court rejected ABB’s argument and ruled that there had “simply been no violation” of either Rule 26(a)(2) or the scheduling order because “[e]vidence of secondary considerations *is in the nature of rebuttal evidence.*” *Id.* at 672 (emphasis added). That is, “a patentee typically comes forward with proof of secondary considerations of validity, or ‘non-obviousness,’ in rebuttal to a patent challenger’s *prima facie* case of obviousness.” *Id.* (citing *Graham*). The Court further noted that “rebuttal” is merely a showing of facts supporting an opposite conclusion, and may relate to any of the *Graham* factors including secondary considerations such as commercial success. *Id.* at 673 (citations omitted). Accordingly, the court held that expert opinions concerning secondary considerations were properly submitted in rebuttal to the opening expert reports concerning invalidity. *Id.*; see also *Poly-America*, 2002 WL 1996561, at *15 (refusing to strike rebuttal expert report regarding secondary considerations of nonobviousness that properly rebutted the “same subject matter” of obviousness in opponent’s opening expert report).

As discussed above, Drs. Kibbe and Spilker both opined at length in their opening expert reports on the alleged obviousness of Wyeth’s asserted claims. [See, e.g., Kibbe Report at ¶¶ 20-55; Spilker Report at ¶¶ 30-41]. In response, Dr. Grabowski’s report provides a detailed analysis of Effexor XR®’s remarkable commercial success in the extremely competitive market for antidepressants, and demonstrates the “nexus” between the patented inventions and the

commercial success of Effexor XR[®].⁶

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See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc. 348 F.Supp.2d 713, 759 (N.D.W.Va. 2004) ().

Impax challenges pages 3-16 of Dr. Grabowski's report, which contains background information, including an overview of the economics of the research-based pharmaceutical industry, the costs and risks associated with drug development, and the incentives that patents provide to the innovative process. However, this testimony is further objective evidence of the merits and nonobviousness of Wyeth's inventions, highlighting how difficult it is to develop a true blockbuster pharmaceutical product notwithstanding the huge expenditures made in pharmaceutical research and development.

To be sure, as Impax notes, Dr. Grabowski also devotes a portion of his Rebuttal Expert Report to responding to Impax's expert Dr. Comanor, who opines that the commercial success of Effexor XR[®] is due to Wyeth's promotion and advertising. Specifically, Dr.

⁶ Wyeth also submitted additional rebuttal expert reports that address other of Impax's allegations of obviousness.

Grabowski explains how Dr. Comanor's economic models are incorrect and unreliable, and how Effexor XR[®] was a tremendous success despite the fact that Wyeth's share of advertising and promotional spending for Effexor XR[®] was significantly less than that of its competitors. Contrary to Impax's assertions, however, Dr. Grabowski's rebuttal to Dr. Comanor is but a small piece of his overall rebuttal to the broad allegations of obviousness raised by Impax's other experts.

2. Dr. Thisted's Rebuttal Expert Report Properly Responds to Dr. Kibbe's Expert Report and Untimely Supplemental Expert Report as well as Dr. Spilker's Expert Report

Impax's experts, Dr. Spilker and Dr. Kibbe, opined that l

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In addition, in his untimely Supplemental Report, Dr. Kibbe offers his opinions regarding an extended release venlafaxine allegedly renders the asserted claims invalid.

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Paragraphs 87 and 88 of Dr. Thisted's rebuttal report also respond to the subject matter of those allegations. There, Dr. Thisted discusses the results of Wyeth's

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Although Dr. Thisted does not expressly reference Dr. Kibbe's opinions on this matter, his opinions are still directed to the "same subject matter," and are therefore proper rebuttal. *See Poly-America*, 2002 WL 1996561 at *19 (refusing to strike a rebuttal expert report even though the expert did not identify whose testimony he was rebutting in either his rebuttal report or at his deposition).

CONCLUSION

For all of the above reasons, Impax's Motion to Strike Portions of the Rebuttal Expert Reports of Dr. Henry Grabowski and Dr. Ronald Thisted should be denied in its entirety.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on January 23, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
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I also certify that copies were caused to be served on January 23, 2008 upon the following in the manner indicated:

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